

PSJ17 Exh 114

1 THE UNITED STATES DISTRICT COURT
2 FOR THE EASTERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL :
5 PRESCRIPTION OPIATE : MDL NO. 2804
6 LITIGATION :
7 -----

8 : CASE NO.
9 THIS DOCUMENT : 1:17-MD-2804
10 RELATES TO ALL CASES: Hon. Dan A. Polster

11 - - -
12 Wednesday, November 28, 2018

13 - - -
14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -
17 Videotaped deposition of JOSEPH
18 TOMKIEWICZ, taken pursuant to notice, was held
19 at Golkow Litigation Services, One Liberty
20 Place, 1650 Market Street, Suite 5150,
21 Philadelphia, Pennsylvania 19103, beginning at
22 9:58 a.m., on the above date, before Lisa V.
23 Feissner, RDR, CRR, Notary Public.

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1 MR. HAMMOUD: Object to the form.

2 THE WITNESS: That is correct.

3 BY MR. CARTMELL:

4 Q. Okay. And what does it mean for a
5 drug or a pharmaceutical like the opioids
6 produced by Teva and sold by Teva, what does it
7 mean to be a controlled substance?

8 A. From my understanding, it is that
9 it's a -- that the manufacture, sale,
10 distribution of the products are controlled
11 federally by the federal government and that --
12 and as part of what's called the closed
13 distribution system.

14 Q. Okay. And I think you mentioned
15 this, but Congress actually passed what's
16 called the Controlled Substances Act that
17 governs and regulates the sale of opioid
18 narcotics and controlled substances?

19 MR. HAMMOUD: Object to the form.

20 THE WITNESS: Correct.

21 BY MR. CARTMELL:

22 Q. Okay. And I think you mentioned
23 this, too, but the Controlled Substances Act
24 went into effect in 1970; is that right?

1 A. That's correct.

2 Q. Okay. I want to actually hand you
3 Exhibit 4 in this case and ask you a few
4 questions about this document.

5 (Exhibit Teva-Tomkiewicz-004 marked
6 for identification and attached to the
7 transcript.)

8 BY MR. CARTMELL:

9 Q. This was a document that was
10 produced in this litigation by Teva from their
11 internal files, and I just have a few questions
12 about this letter for you.

13 This is a letter dated --

14 MR. HAMMOUD: Can you give him a
15 second to read the document.

16 BY MR. CARTMELL:

17 Q. Mr. Tomkiewicz, have you seen this
18 letter before?

19 A. Yes, I have.

20 Q. In other words, you're familiar
21 with this letter based on your experience in
22 the industry related to diversion control of
23 opioid narcotics?

24 A. Yes, I've seen it and have a copy

1 of it.

2 Q. Okay. Now, I think actually we
3 found this letter in your file. But as you see
4 here, this is from the U.S. Department of
5 Justice Drug Enforcement Administration.

6 Do you see that?

7 A. Yes.

8 Q. And we talked -- you kept calling
9 it the administration; I kept calling it the
10 agency. I apologize.

11 A. Administration, yeah.

12 Q. But this is the entity that is --

13 A. I've been wrong before.

14 Q. Don't worry. I am all the time.
15 But this is the entity that is charged with the
16 duty to enforce the act, the Controlled
17 Substances Act, correct?

18 A. My understanding, yes.

19 Q. Okay. And I want to go through a
20 few things here. The date of this is actually
21 February 7th of 2007.

22 Do you see that?

23 A. Yes.

24 Q. So that's actually over ten years

1 ago, correct?

2 A. Correct.

3 Q. And this is a letter from, if you
4 look at the last page, somebody named Joseph
5 Rannazzisi.

6 Do you see that?

7 A. Yes.

8 Q. Okay. And that's a name that
9 you're familiar with, right?

10 A. Yes.

11 Q. And is it true that this letter and
12 maybe some of the additional letters from
13 Mr. Rannazzisi have become well-known to
14 manufacturers and distributors of opioid
15 narcotics? Is that fair?

16 MR. HAMMOUD: Object to the form.

17 THE WITNESS: I would say that that
18 is fair, yeah.

19 BY MR. CARTMELL:

20 Q. Okay. Now, you weren't working at
21 Teva at this time, but let me go through this
22 and ask you some questions about it. But first
23 it states, Dear sir or madam, this letter is
24 being sent to every commercial entity in the

1 United States registered with the Drug
2 Enforcement Administration to distribute
3 controlled substances.

4 Now, let me ask you, is it true
5 that a pharmaceutical company like Teva or a
6 distributor like AmerisourceBergen, they have
7 to register with the DEA in order to be allowed
8 to sell or distribute opioid narcotics?

9 MR. HAMMOUD: Object to the form.

10 THE WITNESS: Or manufacture.

11 BY MR. CARTMELL:

12 Q. Or manufacture?

13 A. Correct.

14 Q. Okay. It states, The purpose of
15 this letter is to reiterate the responsibility
16 of controlled substance distributors in view of
17 the prescription drug abuse problem our nation
18 currently faces.

19 Do you see that?

20 A. Yes.

21 Q. And we've already talked about
22 that, but clearly back in 2007, at that point
23 already our nation was faced with an opioid
24 addiction and abuse problem, correct?

1 MR. HAMMOUD: Object to the form,
2 lacks foundation.

3 THE WITNESS: Well, I'd say that's
4 a fair assessment.

5 BY MR. CARTMELL:

6 Q. Okay. And then it states, As each
7 of you is undoubtedly aware, the abuse or
8 nonmedical use of controlled prescription drugs
9 is a serious and growing health problem in this
10 country.

11 And we've talked about that, and
12 you agree with that, correct?

13 A. Oh, yes.

14 Q. The next paragraph states, The
15 CSA -- and that would be the Controlled
16 Substances Act, right?

17 A. My understanding, yes.

18 Q. -- was designed by Congress to
19 combat diversion by providing for a closed
20 system of drug distribution in which all
21 legitimate handlers of controlled substances
22 must obtain a DEA registration, and as a
23 condition of maintaining such registration,
24 must take reasonable steps to ensure that their

1 registration is not being utilized as a source
2 of diversion.

3 Do you see that?

4 A. Yes.

5 Q. Distributors are, of course, one of
6 the key components of the distribution chain.
7 If the closed system is to function properly as
8 Congress envisioned, distributors must be
9 vigilant in deciding whether a prospective
10 customer can be trusted to deliver controlled
11 substances only for lawful purposes. This
12 responsibility is critical as Congress has
13 expressly declared that the illegal
14 distribution of controlled substances has a
15 substantial and detrimental effect on the
16 health and welfare of the American people.

17 Do you see that?

18 A. Yes.

19 Q. And what this is talking about is
20 that distributors of these drugs and
21 manufacturers of these drugs that are selling
22 these opioid narcotic drugs have a
23 responsibility to try to do everything they can
24 to prevent the diversion of the drugs they are

1 manufacturing, selling, and distributing,
2 correct?

3 MR. HAMMOUD: Object to the form.

4 THE WITNESS: Well, I think, you
5 know, doing everything we can, I think
6 that's a fair assessment.

7 BY MR. CARTMELL:

8 Q. Okay. And then if you go to the
9 next page, I want to talk to you about the
10 second paragraph. Here's where it talks
11 specifically about manufacturers like Teva.

12 In the second sentence it says,
13 Moreover, all registrants -- manufacturers,
14 distributors, pharmacies, and practitioners --
15 share responsibility for maintaining
16 appropriate safeguards against diversion.
17 Nonetheless, given the extent of prescription
18 drug abuse in the United States, along with the
19 dangerous and potentially lethal consequences
20 of such abuse, even just one distributor that
21 uses its DEA registration to facilitate
22 diversion can cause enormous harm.

23 Do you agree with that?

24 A. Yes.

1 Q. Okay.

2 Accordingly, the DEA will use its
3 authority to revoke or suspend registrations in
4 appropriate cases.

5 Do you see that?

6 A. Yes.

7 Q. And that's a fact, right, that DEA,
8 as the enforcer of the law, the Controlled
9 Substances Act, if they find that a
10 manufacturer of opioids or a seller or
11 distributor of opioids is allowing diversion or
12 ignoring diversion, or not taking on their duty
13 to try to prevent diversion and abuse of these
14 drugs, the DEA can take away the registration
15 from that company. Is that fair?

16 A. They have --

17 MR. HAMMOUD: Object to the form.

18 THE WITNESS: I believe they have
19 that ability, yes.

20 BY MR. CARTMELL:

21 Q. And taking away a company's reg --
22 DEA registration is a really big deal. Would
23 you agree with that?

24 A. Oh, I would agree with that, yes.

1 Q. Because if the registration for the
2 company, a company like Teva, is taken away by
3 the DEA, then that company no longer has the
4 ability to sell or distribute these opioid
5 narcotic drugs. Is that fair?

6 A. Or manufacture.

7 Q. Or manufacture them, right?

8 A. Correct.

9 Q. The next paragraph, if you look at
10 the second sentence, states, Listed first among
11 these factors is the duty of distributors to
12 maintain effective controls against diversion
13 of controlled substances into other than
14 legitimate medical, scientific, and industrial
15 channels.

16 Do you see that?

17 A. Yes.

18 Q. And does that mean there is a duty
19 by distributors and manufacturers of these
20 opioids, and sellers of these opioid narcotic
21 drugs, that they have to have controls in place
22 in their organization to help prevent the
23 diversion and abuse of these drugs? Is that
24 what that means?

1 MR. HAMMOUD: Object to the form.

2 MR. NICHOLAS: Object to form.

3 THE WITNESS: And I would say
4 that's a fair assessment.

5 BY MR. CARTMELL:

6 Q. Okay. If you go down to the next
7 paragraph, it states, The DEA regulations
8 require all distributors to report suspicious
9 orders of controlled substances.

10 Do you see that?

11 A. Yes.

12 Q. Now, you talked about you were
13 actually hired by Teva to be the manager of the
14 suspicious order monitoring; is that right?

15 A. Of the suspicious order monitoring
16 program, yes.

17 Q. And when we talk about suspicious
18 orders related to opioids, what are we talking
19 about?

20 A. We're talking about orders that may
21 be of an unusual size, pattern, or frequency.

22 Q. Okay. And I think it says this
23 here. Let's talk about it.

24 The registration -- or excuse me.

1 The registrant shall design and operate a
2 system to disclose to the registrant suspicious
3 orders of controlled substances.

4 Would you agree with me that it's
5 the duty of Teva and all manufacturers and
6 sellers and distributors of these opioids to
7 design a system so that they can, to the best
8 of their ability, have suspicious orders
9 identified?

10 MR. HAMMOUD: Object to the form.

11 THE WITNESS: I would say that's a
12 fair assessment, yes.

13 BY MR. CARTMELL:

14 Q. It then states that the registrant
15 shall inform the field division office of the
16 administration in his area of suspicious orders
17 when discovered by the registrant.

18 Do you see that?

19 A. Yes.

20 Q. And "the registrant" is talking
21 about -- in your case Teva would be the
22 registrant because they have a DEA
23 registration, right?

24 A. Correct.

1 Q. So Teva, according to the law
2 that's been in place since the 1970s, has had,
3 one, the duty to design a system that's
4 effective in helping them to identify the
5 diversion of opioids, correct?

6 MR. HAMMOUD: Object to the form.

7 THE WITNESS: Controlled
8 substances, yes.

9 BY MR. CARTMELL:

10 Q. Including opioids, right?

11 A. Correct.

12 Q. And also they've got to operate a
13 system that's effective in disclosing
14 suspicious orders that come to them for these
15 opioids, correct?

16 A. Correct.

17 Q. Okay. And that's been going on --
18 that's been the duty of companies like Teva and
19 distributors of opioids, that duty has existed
20 since the 1970s, correct?

21 MR. HAMMOUD: Object to the form.

22 THE WITNESS: I'm not certain when
23 the reg came into effect, but I'll take
24 your word as an attorney.

1 BY MR. CARTMELL:

2 Q. Well, you know that that -- and I
3 don't mean to put words in your mouth, but I
4 take it from your experience, you know that
5 this duty that we've been talking about, to
6 have a suspicious order monitoring system, one
7 that is effective, that duty has been in effect
8 since before the 1990s. Fair enough?

9 A. Oh, that's fair.

10 Q. If you go a couple paragraphs down,
11 it says, Thus, in addition to reporting all
12 suspicious orders, a distributor has a
13 statutory responsibility to exercise due
14 diligence to avoid filling suspicious orders
15 that might be diverted into
16 other-than-legitimate medical, scientific, and
17 industrial channels.

18 Do you see that?

19 A. Yes.

20 Q. And that's the law, right?

21 MR. HAMMOUD: Object to the form,
22 calls for a legal conclusion.

23 THE WITNESS: And that's my
24 understanding.

1 BY MR. CARTMELL:

2 Q. I should say that's your
3 understanding of the law as a suspicious order
4 monitoring manager at Teva. Is that fair?

5 A. That is a fair assessment, yes.

6 Q. In other words, your understanding
7 as the manager at Teva since 2014 has been that
8 if your company determines that there are
9 suspicious orders for opioid narcotic drugs
10 that has come to your company, you have the
11 duty to report that to the DEA, correct?

12 MR. HAMMOUD: Object to the form.

13 THE WITNESS: That is correct.

14 BY MR. CARTMELL:

15 Q. And is it true that you also have
16 the duty -- when your company determines that
17 one of your customers has a suspicious order,
18 you have the duty to, in fact, stop that order
19 from being shipped so that it won't likely be
20 diverted out in the community?

21 MR. HAMMOUD: Object to the form,
22 calls for a legal conclusion.

23 THE WITNESS: Yeah, I haven't heard
24 that there's a regulatory requirement to

1 stop it, but I will say that I don't
2 ship anything that we have determined to
3 be suspicious.

4 BY MR. CARTMELL:

5 Q. In other words, would you agree
6 with me that the most prudent practice and the
7 most responsible practice would be that if a
8 company like Teva and its manager like you
9 determines that orders are suspicious for these
10 opioids that are narcotics and that you know
11 can be diverted and abused so readily, the best
12 practice and the most responsible practice
13 would be not to ship those orders? Do you
14 agree with that?

15 MR. HAMMOUD: Object to the form.

16 THE WITNESS: I would agree to
17 that.

18 BY MR. CARTMELL:

19 Q. Okay. It then states, In a similar
20 vein, given the requirement under Section
21 823(e) that a distributor maintain effective
22 controls against diversion, a distributor may
23 not simply rely on the fact that the person
24 placing the suspicious order is a DEA

1 registrant and turn a blind eye to the
2 suspicious circumstances.

3 Do you see that?

4 A. Yes.

5 Q. In other words, that means that a
6 company like Teva, if you have an order for
7 opioids that you think may be suspicious and
8 could likely be diverted or abused out in the
9 communities, you can't turn a blind eye and
10 just say, well, I'll go ahead and ship it
11 because the person who made the order is
12 registered with the DEA. You can't do that,
13 right?

14 MR. HAMMOUD: Object to the form.

15 THE WITNESS: And I would say that
16 yes, that is correct.

17 BY MR. CARTMELL:

18 Q. And just on the -- I don't want to
19 go through them, but if you turn the page,
20 Mr. Tomkiewicz, you'll see that there are
21 actually some hints by the DEA here that were
22 given to distributors and manufacturers of
23 these opioids as far as some things that might
24 be a clue that an order might be suspicious or

1 may be ultimately diverted.

2 Do you see that?

3 A. Yes.

4 Q. You can see that they give
5 circumstances that might be indicative of
6 diversion, right?

7 A. Correct.

8 Q. And you're very familiar with those
9 circumstances, I take it?

10 A. Yes, I'm familiar with them.

11 Q. And you take those circumstances or
12 these hints that are given by the DEA into
13 consideration as the manager that is monitoring
14 suspicious orders. Is that fair to say?

15 A. These specifically, when I'm
16 reviewing -- when we're reviewing things that
17 might be suspicious, I wouldn't say we refer
18 back to this document, but they're often
19 included in, you know, how we review.

20 Q. Okay. In other words, you're
21 saying, I don't get the document out, but these
22 are some of the things we look for when we're
23 looking for a suspicious order of opioid
24 narcotic drugs, right?

1 A. Or any controlled substance, yes.

2 Q. Okay. Now, if you go back to the
3 first page, this letter, which is often
4 referred to as the Rannazzisi letter, was --
5 well, let me ask you if you agree with me.

6 This letter that was sent from the
7 Drug Enforcement Administration to all of the
8 manufacturers and sellers and distributors of
9 opioids, including the high-risk opioids that
10 are narcotics and easily diverted, this was
11 sort of a reminder to these manufacturers,
12 sellers, and distributors of the
13 responsibilities and duties they had to help
14 prevent diversions of opioids. Would you agree
15 with that?

16 MR. HAMMOUD: Object to the form.

17 THE WITNESS: And I would not agree
18 with the assessment in your question
19 that certain high-risk, at least as I
20 define them, are easily diverted. I --

21 BY MR. CARTMELL:

22 Q. Okay, well, let me restate --

23 A. -- I would --

24 Q. Fair enough.

1 A. Yeah, I would reject that.

2 Q. Fair enough. Let me restate the
3 question.

4 Would you agree with me that this
5 letter that's often referred to as the
6 Rannazzisi letter was the Drug Enforcement
7 Agency sending a letter to manufacturers,
8 distributors, sellers of opioid narcotic drugs
9 as sort of a reminder and reiterating the
10 duties and responsibilities that they had to
11 try to prevent the diversion of opioid narcotic
12 drugs? Fair enough?

13 MR. HAMMOUD: Object to the form.

14 THE WITNESS: And I would say
15 that's a fair assessment.

16 BY MR. CARTMELL:

17 Q. Okay. Do you know, as you sit here
18 today, when it was that Teva first started
19 selling or distributing opioids?

20 A. No, I don't.

21 Q. Do you have any clue?

22 MR. HAMMOUD: Objection, asked and
23 answered.

24 THE WITNESS: I have no idea.

1 BY MR. CARTMELL:

2 Q. Okay. It should be noted, though,
3 I think, that when you arrived at Teva in 2014,
4 at that point I take it you know that they were
5 selling lots of different Class II opioid
6 products. Is that fair?

7 MR. HAMMOUD: Object to the form,
8 lacks foundation.

9 THE WITNESS: And -- sorry, but I
10 don't like the term "lots." I like
11 using numbers.

12 BY MR. CARTMELL:

13 Q. Well, I counted, from the documents
14 I received, that today, Teva is selling, I
15 believe, 18 or 19 Class II opioid narcotic
16 drugs. Is that consistent with your
17 understanding?

18 A. That could be consistent, yes.

19 Q. And I said "lots." But when you
20 arrived in 2014, is it fair to say that Teva
21 was selling a number of different opioid --
22 Class II opioid narcotic drugs? Fair to say?

23 MR. HAMMOUD: Object to the form.

24 THE WITNESS: I would say that's

1 fair to say.

2 BY MR. CARTMELL:

3 Q. And fair to say that Teva sells and
4 distributes millions of prescriptions for
5 opioid narcotic drugs? Fair?

6 MR. HAMMOUD: Object to the form.

7 THE WITNESS: We don't dispense
8 prescriptions.

9 BY MR. CARTMELL:

10 Q. Bad question. Thank you for
11 correcting that.

12 Is it fair to say that Teva sells
13 and distributes millions and millions of opioid
14 narcotic drug pills per year?

15 MR. HAMMOUD: Object to the form.

16 THE WITNESS: I haven't looked at
17 the specific number of dosage units, but
18 I'm sure it's in the millions. But
19 beyond that, I couldn't say millions and
20 millions. And to say -- we've sold a
21 good number of them.

22 BY MR. CARTMELL:

23 Q. And I think I've seen data that
24 suggests that today, or since 2016, Teva has

1 been, as far as the sales of opioid drugs,
2 about at the 9 to 10 percent of the sales are
3 of Teva opioid products. Is that consistent
4 with your understanding?

5 MR. HAMMOUD: Object to the form,
6 lacks foundation.

7 THE WITNESS: I don't know that
8 offhand.

9 BY MR. CARTMELL:

10 Q. But you agree that Teva is one of
11 the larger sellers and distributors of opioid
12 narcotic drugs in America, correct?

13 A. I would say that's a fair
14 assessment, yes.

15 Q. And those are all things that, when
16 you came to Teva, some of the things that you
17 looked into, I take it, and learned as you
18 started in your job as the new suspicious order
19 manager; is that right?

20 A. Right. Well, looking at the -- you
21 know, which specific products we were selling,
22 which, of course, was a different mix when I
23 started from what is currently being sold.

24 Q. We talked about the law, the

1 Controlled Substances Act, and the DEA
2 enforcement of a law related to the sales of
3 opioids in America. And is it true that the
4 DEA has actually left the responsibility to the
5 manufacturers and sellers and distributors of
6 opioids to design, internally, systems to help
7 prevent opioid diversion?

8 MR. HAMMOUD: Objection to the
9 form.

10 THE WITNESS: Could you ask that
11 again? I got lost in the question.

12 BY MR. CARTMELL:

13 Q. Sure. Is it true that the DEA has
14 left the responsibility or relies on the
15 manufacturers and distributors and sellers of
16 opioid narcotic drugs in America to develop the
17 systems to help divert -- their internal
18 systems to help divert opioids -- help to
19 prevent the diversion of opioids?

20 A. So are --

21 MR. HAMMOUD: Same objection.

22 THE WITNESS: Yeah, are you saying
23 that the DEA has sort of left the
24 manufacturers on their own to develop

1 their own system to detect potential
2 diversion?

3 BY MR. CARTMELL:

4 Q. Let me restate the question to make
5 it more clear.

6 As we saw from the Controlled
7 Substances Act, it requires manufacturers like
8 Teva to develop internal systems that will
9 help, for one thing, identify suspicious orders
10 of opioids, right?

11 A. Correct.

12 Q. It also said in the Controlled
13 Substances Act that manufacturers like Teva who
14 sell opioids have to design systems internally
15 to help prevent the diversion of opioids,
16 correct?

17 MR. HAMMOUD: Object to the form.

18 THE WITNESS: Of any controlled
19 substance.

20 BY MR. CARTMELL:

21 Q. Including opioids, right?

22 A. Yes.

23 Q. And is it true that the DEA
24 actually relies on Teva and the individual

1 manufacturers and sellers and distributors of
2 opioids to, in fact, develop those systems and
3 make sure they have effective systems in place
4 and monitoring programs in place so that they
5 can help divert the -- or help prevent the
6 diversion of opioids?

7 MR. HAMMOUD: Same objection.

8 THE WITNESS: And I wouldn't say --
9 I couldn't say that the DEA relies on
10 manufacturers and distributors for that.
11 Because when it comes to suspicious
12 order monitoring, they really haven't
13 given any feedback.

14 BY MR. CARTMELL:

15 Q. Okay. But you know from the
16 Controlled Substances Act that you have to have
17 systems in place --

18 A. Correct.

19 Q. -- right? And the DEA does not
20 develop those systems for you, correct?

21 A. The DEA has not developed our
22 system, no.

23 Q. Okay. And so you are left as a
24 manufacturer, meaning Teva, of these opioids to

1 develop those systems yourself, correct?

2 A. Correct.

3 Q. And the DEA does rely on each of
4 the companies like Teva to develop those
5 systems to help prevent opioid diversion,
6 correct?

7 MR. HAMMOUD: Object to the form.

8 THE WITNESS: Well, and again, I
9 can't say that the DEA relies on because
10 I don't know what the DEA is doing on
11 their end. So in terms of, you know,
12 saying that the DEA relies on, you know,
13 manufacturers or distributors or even
14 down to pharmacies or practitioners, I
15 can't say that.

16 BY MR. CARTMELL:

17 Q. Okay. One of the things, though,
18 that companies like Teva, as we discussed, are
19 interested in is maximizing the sales of their
20 prescription drugs like opioids, including
21 opioids, correct?

22 MR. HAMMOUD: Object to the form,
23 lacks foundation.

24 THE WITNESS: Maximizing? I think

1 that's a horrible word for it. No
2 offense, but...

3 BY MR. CARTMELL:

4 Q. How would you describe it?

5 A. Companies want to increase
6 profitability. That's the reason why people
7 are in business.

8 Q. Mr. Tomkiewicz, the DEA, as we saw,
9 has told Teva and companies like Teva who sell
10 and distribute opioids to set up systems that
11 will identify suspicious orders of opioids,
12 correct?

13 A. Correct.

14 Q. And they've asked those companies
15 to take it upon themselves to provide the
16 resources and actual processes to put in
17 effective types of monitoring programs to find
18 suspicious orders, correct?

19 MR. HAMMOUD: Object to the form.

20 THE WITNESS: I would say that's a
21 fair assessment.

22 BY MR. CARTMELL:

23 Q. And these same companies that the
24 DEA has asked to set up these systems so that

1 they can find these suspicious orders are
2 companies like Teva who, as you said, are
3 interested in maximizing their profits,
4 correct?

5 A. I never said that.

6 MR. HAMMOUD: Objection,
7 mischaracterizes his testimony.

8 THE WITNESS: In fact, I
9 categorically denied the word
10 "maximize."

11 BY MR. CARTMELL:

12 Q. How did you describe it? I'll use
13 your words.

14 A. I said that any company wants to
15 increase profits. That's why you're in
16 business.

17 Q. So these companies that the DEA has
18 asked to set up these systems to help prevent
19 the diversion of opioids are the same companies
20 that want to increase their profits, correct?

21 A. I think that's a goal of business.

22 Q. And part of increasing profits, as
23 we've discussed, is potentially, or can be,
24 increasing their sales, correct?

1 A. Correct.

2 Q. So they're asking companies that
3 want to increase their sales and increase their
4 profits to set up systems that could, if they
5 find suspicious orders, decrease their sales,
6 correct?

7 MR. HAMMOUD: Object to the form.

8 THE WITNESS: Well, and that's --
9 that is correct. I would say that's a
10 fair assessment.

11 BY MR. CARTMELL:

12 Q. So these same companies that
13 they're saying that we want you to identify
14 these orders that are suspicious, and we want
15 you to make sure that they are stopped so
16 they're not diverted, are the same companies
17 that want to increase sales and increase
18 profits over time, correct?

19 A. Well, it's going to be difficult to
20 increase sales if you don't have a DEA
21 registration.

22 Q. I understand that, but my point is
23 simply that there is an inherent conflict in
24 that system, correct?

1 A. Well, that's what I'm saying.

2 There isn't an inherent conflict.

3 Q. You don't believe that's a conflict
4 or sort of, so to speak, the fox guarding the
5 hen house?

6 A. No.

7 MR. HAMMOUD: Object to the form.

8 MR. CARTMELL: How long have we
9 been going?

10 MR. HAMMOUD: About an hour and
11 three minutes.

12 MR. CARTMELL: Do you want to take
13 a quick break?

14 THE WITNESS: A break sounds good.

15 MR. CARTMELL: Like ten minutes?

16 VIDEO OPERATOR: Going off the
17 record, 2 p.m.

18 (Recess from 2:03 p.m. until
19 2:15 p.m.)

20 VIDEO OPERATOR: Back on record at
21 2:15 p.m.

22 BY MR. CARTMELL:

23 Q. Mr. Tomkiewicz, we're back on the
24 record. Are you ready to proceed?

1 A. Yes, I am.

2 Q. I want to ask you a few more
3 questions about Exhibit 3. I think it's in
4 front of you. And this was the PowerPoint
5 presentation from March of 2014, which was just
6 a few months after you arrived at the company
7 to start working, correct?

8 A. Correct.

9 Q. And if we look at page 3, as we
10 discussed, there was a proposed DEA compliance
11 organization, and as we discussed, there was a
12 small restructuring or a few people moving
13 around, according to this proposed
14 organization; is that correct?

15 A. Correct.

16 Q. And did that small restructuring
17 occur at that time; do you know?

18 A. I believe it did.

19 Q. Okay. And if you look at where you
20 are, Joe Tomkiewicz, it states under you, you
21 had one individual reporting to you, Matt
22 Benkert; is that right?

23 A. That's correct.

24 Q. And his position was -- it

1 But when you stopped selling them,
2 at that point in time, you did not know about
3 the investigation into their sales --

4 A. Exactly.

5 Q. -- of opioids?

6 A. Exactly.

7 MR. HAMMOUD: Are we about at a
8 good place for a break?

9 MR. CARTMELL: We've been going for
10 an hour probably?

11 MR. HAMMOUD: A little over an
12 hour, yeah.

13 MR. CARTMELL: How far are we in?

14 VIDEO OPERATOR: 5:50. We've been
15 going for an hour and 22 minutes.

16 MR. CARTMELL: Yeah, let's take a
17 break.

18 MR. HAMMOUD: Okay. Thanks.

19 VIDEO OPERATOR: Going off the
20 record, 5:22.

21 (Recess from 5:22 p.m. until
22 5:38 p.m.)

23 VIDEO OPERATOR: Back on the record
24 at 5:38 p.m.

1 BY MR. CARTMELL:

2 Q. Mr. Tomkiewicz, we're back on the
3 record. Are you ready to proceed?

4 A. I am ready.

5 Q. Okay. So I want to go back to
6 Exhibit 5. I forgot to ask you something about
7 that at page 37.

8 And we talked about this slide that
9 you created in 2014 for the things you were
10 going to do in the future for the program --
11 suspicious order monitoring program at Teva.

12 The last thing that we didn't talk
13 about was chargeback data. Do you see that?

14 A. Yes.

15 Q. Okay. So first of all, do you know
16 whether or not Teva was actually using
17 chargeback data to try to help them identify
18 suspicious orders prior to 2014, when you
19 started there?

20 A. I don't believe they were, but I
21 don't know for certain.

22 Q. Okay. Now, chargeback data, I
23 believe the DEA has said, is an advisable
24 resource to use in order to try to identify

1 suspicious orders; is that correct?

2 A. That's my understanding, yes.

3 Q. Okay. And Teva, before the time
4 you got there, had chargeback data that they
5 could have used to try to help them identify
6 suspicious orders, correct?

7 A. That's correct.

8 Q. But they chose not to do that; is
9 that right?

10 MR. HAMMOUD: Objection. Object to
11 the form.

12 THE WITNESS: Yeah, I don't know.

13 BY MR. CARTMELL:

14 Q. But let me ask you this. When you
15 were at AmerisourceBergen and managing that
16 suspicious order monitoring program, did your
17 program include a review of chargeback data to
18 try to help you or assist you in identifying
19 suspicious orders?

20 A. Oh, not at all.

21 Q. You didn't use it?

22 A. Not at all, because --

23 And your question says that you
24 don't understand what chargeback data is.

1 Q. My question says to you that I
2 don't understand what chargeback data is?

3 A. Yes.

4 Q. Exactly right.

5 A. Would you like me to explain it?

6 Q. Yes.

7 A. Okay. Chargeback data. What a
8 chargeback is, is when, say, my company,
9 Teva -- sorry for hitting the microphone --
10 when my company, Teva, contracts with either a
11 pharmacy, a hospital, a buying group that
12 represents pharmacies and we grant a contract
13 price on a product to, you know, that group,
14 that entity, then for a wholesaler who buys at
15 wholesale acquisition cost who services those
16 pharmacies with whom we have the contract, that
17 wholesaler, say, AmerisourceBergen, will
18 provide that product at the contract cost to
19 the pharmacy, the hospital, the entity, the
20 hospice, whomever, and then charge back the
21 difference back to Teva.

22 And then that contract price in the
23 data that comes back will have information on
24 the customer, the product, the quantity,

1 information supporting that this product went
2 to this customer for that customer.

3 Now, what that doesn't include are
4 customers who don't have contracts, customers
5 who buy from wholesalers who buy at contract
6 price who aren't buying at wholesale
7 acquisition cost. It's not going to include
8 distributors are who are, say, owned by a large
9 retail chain.

10 And so from the wholesaler's
11 standpoint, when I was at AmerisourceBergen,
12 there was no need to review chargeback data
13 because we saw everything that we sold to the
14 customer.

15 Now, on the Teva side, we can
16 see -- you know, AmerisourceBergen, for
17 example, we can see where they sold our product
18 at contract price to their customers. But if a
19 customer isn't buying on contract price, we
20 don't see that.

21 Q. I understand.

22 Really, what you're saying is, my
23 question was a dumb one, because it wouldn't
24 apply to wholesale distributors; they wouldn't

1 use that; they don't need to use that data.

2 A. Well, and I wouldn't use the
3 prejudicial term "dumb."

4 Q. Okay.

5 A. But maybe ignorant, but --

6 Q. No, I do understand a little bit
7 about it, but that makes sense.

8 A. Yeah.

9 Q. So at any rate, when you arrived at
10 Teva in 2014, one of the other improvements to
11 the suspicious order monitoring program was
12 that you were going to have Teva start to
13 utilize the chargeback data to try to aid and
14 assist in identifying suspicious orders,
15 correct?

16 MR. HAMMOUD: Object to the form.
17 Mischaracterizes prior testimony.

18 THE WITNESS: I will say that's a
19 fair assessment, correct.

20 BY MR. CARTMELL:

21 Q. Okay. And is there other data that
22 you believed that Teva should be using but they
23 weren't other than chargeback data to try to
24 assist with this?

1 And there's something called 867
2 data; is that right?

3 A. Yes, there's 867 data.

4 Q. And did you start Teva into using
5 that type of data as well to try to identify
6 suspicious orders?

7 A. I have started using 867 data, yes.

8 Q. When was that started by the
9 company?

10 A. I think that was in 2017 that I
11 started using that.

12 Q. And has that also assisted Teva in
13 identifying suspicious orders?

14 A. Not only suspicious orders but
15 suspicious customers of our customers.

16 Q. And that's a good point.

17 A. Yes.

18 Q. What you just said is, by using
19 data like chargeback data and 867 data, your
20 company, Teva, can actually look downstream
21 from your customers at your customers'
22 customers, right?

23 MR. HAMMOUD: Objection to the
24 form. Mischaracterizes prior testimony.

1 THE WITNESS: Well, it assists in
2 our investigations, yes.

3 BY MR. CARTMELL:

4 Q. Right.

5 And I'm saying it assists in your
6 investigation of not only looking at whether
7 your customers are potentially asking for
8 suspicious orders, but it also can assist you
9 in looking downstream from your customer to
10 their customers to see whether or not they are
11 potentially violating the law, correct?

12 MR. HAMMOUD: Objection to the
13 form.

14 Go ahead.

15 THE WITNESS: I wouldn't say
16 "violating the law." Just looking for
17 patterns.

18 BY MR. CARTMELL:

19 Q. I understand.

20 But if you do look at that data and
21 you find out that one of your
22 customer's customers, for example -- let's use
23 an example.

24 Teva has customers like

1 AmerisourceBergen, correct?

2 A. Mm-hmm.

3 Q. A large wholesale distributor, as
4 we said, who distributes opioid narcotics all
5 over the United States, correct?

6 A. Correct.

7 Q. If Teva is looking at a potentially
8 suspicious order from AmerisourceBergen, for
9 example, and they do some investigation into
10 that and they find from that investigation --

11 For example, the top ten customers
12 of AmerisourceBergen, they might look into who
13 those people are, correct?

14 A. Correct.

15 Q. If you found out -- for example, if
16 AmerisourceBergen gave their top ten pharmacies
17 that they were selling to and during your
18 investigation, you found out that there were
19 suspicious things about those orders, that
20 would be investigation that I would categorize
21 as downstream investigation to your customer's
22 customer. Correct?

23 MR. NICHOLAS: Object to the form.

24 BY MR. CARTMELL:

1 Q. Correct?

2 A. I would say that's a fair
3 assessment, yes.

4 Q. Okay. And if during that
5 investigation, you identify pharmacies who, it
6 looks like to you, are suspicious for diverting
7 opioids or violating the law or doctors who, it
8 looks suspicious to you, potentially are
9 diverting opioids or violating the law, you, as
10 Teva, have a duty to report that, correct?

11 MR. HAMMOUD: Objection to the
12 form. Calls for a legal conclusion.

13 THE WITNESS: Well, a couple points
14 of clarification.

15 I don't see prescribers with that
16 data, the 867 data level or at the
17 chargeback data. So unfortunately, I
18 don't see prescribers.

19 But I do see pharmacies, and if I
20 do see something that I would classify
21 as a suspicious order at that point --

22 For example, if I were to see an
23 invoice from a wholesaler to a pharmacy
24 that I would consider suspicious, I have

1 reported orders like that, that it's not
2 my order, but it's my customer's order
3 to a pharmacy.

4 BY MR. CARTMELL:

5 Q. Your customer's customer?

6 A. My customer's customer, yes.

7 Q. And you have a duty, just like with
8 your customers, to report that if you believe
9 that is suspicious, correct?

10 MR. HAMMOUD: Objection to the
11 form. Calls for a legal conclusion,
12 asked and answered.

13 THE WITNESS: I would say I have a
14 duty to report suspicious orders.

15 BY MR. CARTMELL:

16 Q. Okay. Including if it's your
17 customer's customer, correct?

18 MR. HAMMOUD: Objection. Asked and
19 answered, calls for a legal conclusion.

20 THE WITNESS: And if I see a
21 suspicious order at my customer's
22 customer level, I will report it, and I
23 have reported it.

24 BY MR. CARTMELL:

1 Q. And that's because it's your duty,
2 you believe, correct?

3 MR. HAMMOUD: Objection. Asked and
4 answered multiple times, calls for a
5 legal conclusion.

6 BY MR. CARTMELL:

7 Q. You can answer.

8 A. I have a duty to report suspicious
9 orders.

10 Q. Okay. Now, we talked a little bit
11 about the policy at Teva that you helped to
12 draft and put into effect in 2014 related to
13 suspicious order monitoring and, specifically,
14 holding of the orders to investigate and decide
15 whether or not they're suspicious and should be
16 shipped. We talked some about that. Do you
17 recall that?

18 A. Yes.

19 Q. Okay. As we know from the policy
20 that you put into effect at -- into writing at
21 Teva, that policy includes not only members of
22 the DEA compliance section that you work in,
23 but also members of parts of the company that
24 have sales as a part of their duties, correct?

1 answered.

2 THE WITNESS: Yeah, and Florida
3 wouldn't have been the only reason to
4 hold the product.

5 BY MR. CARTMELL:

6 Q. It's just one red flag, right?

7 A. It was just another red flag.

8 Q. These red flags are what led you to
9 go further and do more investigation, correct?

10 A. That red flag wouldn't have been
11 one to make me go further down the line.

12 Q. What made you go further down the
13 line and do actual research into the customer's
14 customer?

15 A. That was going to be the --
16 primarily the strength mix of what they were
17 looking for, that it was hyped [sic] to the
18 40-milligram product, that that was the top
19 strength that they were looking for.

20 Q. And because you saw that they were
21 ordering so much of this 40-milligram, or one
22 of the higher strengths, you wanted to see
23 where these drugs were actually going from
24 Publix?

1 A. Well, and not the volume of it but
2 the ratio of the 40-milligram compared to the
3 20-milligram, the 10-milligram, the
4 80-milligram, that the 40 was the top one. And
5 I felt that was unusual and warranted
6 investigation.

7 Q. Okay. And then you went to work
8 and you actually did -- like you said earlier,
9 I think, you got online and you did some
10 Google-type searches and things like that, did
11 you not?

12 A. Well, did some Google searches,
13 looked at the -- you know, verified licenses of
14 prescribers, looked for -- you know,
15 essentially telling the story of who the
16 prescribers are of these products. And not
17 necessarily the products that we were intending
18 to sell to Publix but actually the
19 immediate-release product that was another
20 company's product. So what I was investigating
21 wasn't our product, it was another company's
22 product.

23 Q. Okay. Let's see what your
24 investigation found. And you say that and

1 summarize that in your e-mail below of
2 Wednesday, October 28th, to Colleen McGinn,
3 your boss, correct?

4 A. Correct. Because this primarily
5 involves another company's product, yes.

6 Q. Okay. And you say, On October 27,
7 2015, I received data concerning oxycodone
8 usage at Publix Super Market, Inc. The data
9 comprised of total dosage units dispensed of
10 all oxycodone tablet SKUs for the month of
11 September 2015 for their top ten locations,
12 along with a list of the top five oxycodone
13 prescribers for each location. The following
14 is an analysis of that data.

15 Right?

16 A. Correct.

17 Q. Okay. And you had asked Publix,
18 right -- you had asked the salespeople to go to
19 Publix and get information relating to their
20 top ten locations, along with their top
21 prescribers, correct?

22 A. Correct.

23 Q. And Publix -- the salespeople were
24 able to get that data so that you could look at

1 Q. And ultimately, sir, is it true
2 that, in fact, you didn't report any of these
3 Publix pharmacies, did you?

4 A. I didn't see any specific orders of
5 ours that were being filled by these
6 physicians. Again, these physicians [sic] were
7 for a different product, for oxycodone
8 30-milligram immediate release, which was not
9 our product.

10 Q. Is your testimony that if you find
11 suspicious activity that you say is that bad,
12 is clear in your mind, that even -- just
13 because it's not your product, you don't have
14 to report it to the DEA?

15 MR. HAMMOUD: Objection to the
16 form.

17 BY MR. CARTMELL:

18 Q. Is that your testimony?

19 MR. HAMMOUD: Calls for a legal
20 conclusion.

21 THE WITNESS: If I had seen an
22 order, I would have reported it for
23 those products. But I did not see an
24 order for oxycodone 30-milligram

1 immediate release because we did not
2 have that product at that time.

3 BY MR. CARTMELL:

4 Q. So I want the jury to be clear
5 about this. Even though you did this
6 investigation and found all of this data that
7 you found to be truly indicative and bad of
8 diversionary activity, and you knew doctors
9 were using those pharmacies for that purpose of
10 getting opioids, you released the product
11 because you said, that wasn't our product, so
12 we don't have to report it. Correct?

13 MR. HAMMOUD: Objection to the
14 form.

15 THE WITNESS: And again, I did not
16 see anything suspicious specifically to
17 our product, to our orders.

18 BY MR. CARTMELL:

19 Q. And so because it wasn't --

20 A. So there was nothing to report.

21 Q. -- your product, you didn't report
22 anything, did you?

23 MR. HAMMOUD: Objection to the
24 form.

1 BY MR. CARTMELL:

2 Q. Did you?

3 A. I didn't see any orders. I had no
4 orders to report.

5 Q. Publix ordered from your company --

6 MR. HAMMOUD: Tom, time is up.

7 MR. CARTMELL: Hold on.

8 MR. HAMMOUD: I'll give you the
9 professional courtesy of one more
10 question, but that's it.

11 BY MR. CARTMELL:

12 Q. Publix ordered from your pharmacy
13 generic 30 milligrams oxycodone, correct?

14 A. Wrong.

15 Q. What did they order from you?

16 MR. HAMMOUD: That's it. Time is
17 up.

18 THE WITNESS: Time's up.

19 MR. CARTMELL: I've got like three
20 questions.

21 MR. HAMMOUD: Okay. I'll give you
22 three questions.

23 THE WITNESS: Extended-release
24 oxycodone.

1 BY MR. CARTMELL:

2 Q. So these Publix pharmacies were
3 ordering opioids from your company, correct?

4 A. Correct.

5 Q. Those orders were flagged as
6 suspicious, and then you detailed to sales red
7 flags related to those orders, didn't you?

8 A. Wrong.

9 MR. HAMMOUD: Objection to the
10 form.

11 THE WITNESS: Wrong. They were not
12 flagged as suspicious.

13 BY MR. CARTMELL:

14 Q. They were flagged as potentially
15 suspicious, correct?

16 MR. HAMMOUD: Objection to the
17 form.

18 THE WITNESS: I would say that
19 there was something that -- as I
20 previously said, that they were
21 indicative of things that I felt could
22 be deficient with Publix' program.

23 BY MR. CARTMELL:

24 Q. Potentially suspicious, correct?